Comprehensive Staff Education and Implementation of a Checklist Tool to Increase Staff Adherence to Pitocin Titration Protocols

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Doctor of Nursing Practice

07 / 01 / 2019
Date: ________________

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School of Nursing

Comprehensive Staff Education and Implementation of a Checklist Tool
to Increase Staff Adherence to Pitocin Titration Protocols

A doctoral project submitted in partial satisfaction
of the requirements for the degree of
Doctor of Nursing Practice

by
Tara N. Cassell
August, 2019
Dedication

For Cory, Colton, and Cameron, who are the why for everything I do.
Acknowledgments

I would like to acknowledge the people without whose support and guidance throughout this process I would not have been successful. Thank you to Sharon Fassino, DNP, APRN, NNP-BC, and Jenn Light, DNP, CNM, for mentoring me through the development of my project idea and design; to Dr. Lawrence Santiago, Dr. Sandra Cleveland, and Dr. Linda Gibson for constructive criticism and guidance through the development of each step of this project; and to Mindy Foster MSN, RN, and Lori Abdalla BSN, RN, for trusting me with the opportunity to explore, create, develop, and implement a project on your unit.

I would also like to thank my husband, my parents, and my mother-in-law and my sister-in-law for always being available to watch our children so I could “just get a little schoolwork done,” and my boys for being patient while “Mommy is doing homework right now.” Without this great family support system, I would not have had the time or mental strength to complete this undertaking.
Abstract

This quality improvement project was designed to increase staff adherence to an existing Pitocin titration protocol used in a labor and delivery unit at a community hospital. In the current U.S. health care climate, safe patient care is paramount and the Institute for Safe Medication Practices identified Pitocin as a high-alert medication. Evidence-based practice recommends the use of a titration protocol to guide proper use of Pitocin. Prior research has shown improvements in patient outcomes when facilities implement Pitocin titration protocols, with staff adherence key to the successful implementation of evidence-based titration protocols, which may be improved with the use of adult learning techniques. This project therefore utilized Knowles’s adult learning theory and Donabedian’s quality of care framework to inform the improvement measures. The results showed a statistically significant increase in staff adherence to the Pitocin titration protocol and a trend of improvement in most measured patient outcomes.

Keywords: Pitocin titration, oxytocin, labor augmentation, staff education, training
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Chapter 1: Introduction

Delivery of safe patient care is paramount in today’s U.S. health care climate. Standards of care have been developed to ensure patients get the appropriate care, and policies and protocols have been put into place to guide the safe delivery of care to every patient (Joint Commission, 2017). However, evidence-based knowledge and protocols are only effective if used appropriately, and clinical implementation of evidence-based guidelines is not always the reality (Holmgren, Silfver, Lind, & Nordström, 2011). The failure of a nurse to follow a protocol can lead to preventable patient harm and unfavorable or undesired outcomes (Doyle, Kenny, Burkett, & von Gruenigen, 2011). Nurses, doctors, and hospital systems are vulnerable to litigation and the responsibility of financial compensation for patient harm that results from the failure of the medical professional to follow policies and protocols (Drummond, 2018; Page, McCool, & Guidera, 2017; Sohn, 2013).

Oxytocin is a hormone native to a woman’s body and serves several functions, the most notable being its role in stimulating uterine contractions during labor (Wojnar, Cowgill, Hoffman, & Carlson, 2014). Pitocin is the synthetic form of oxytocin and is used in obstetrics for induction and augmentation of labor in approximately 50% of labors in the United States (Clark, Simpson, Knox, & Garite, 2009; Drummond, 2018; Holmgren et al., 2011; Krening, Rehling-Anthony, & Garko, 2012; Mahlmeister, 2008; Page et al., 2017). When used correctly, Pitocin is safe; however, when used inappropriately, it has the potential for great harm. For this reason, the Institute for Safe Medication Practices (ISMP, 2014) placed Pitocin on the high-alert medication list. According to the ISMP (2014), a high-alert medication is “one that bear[s] a heightened risk of causing significant patient harm when used in error” (para. 1). Following this high-alert designation, the risks and benefits of oxytocin administration have been studied more
extensively, leading to implementation of Pitocin titration protocol recommendations to reduce the risk for the patient. Given the recent focus on patient safety and quality of care, implementing checklists and protocols is an important feature of care for obstetrical care providers (Arora et al., 2016; Drummond, 2018; Page et al., 2017).

Drummond (2018) and Mahlmeister (2008) pointed out that an important initial step in the success of a risk-reducing protocol is team education. Sustaining a clinical practice change is challenging, and physician involvement is critical to success (Doyle et al., 2011; Krening et al., 2012; Page et al., 2017).

**Problem Statement**

To effectively and safely augment labor, labor and delivery nurses must titrate Pitocin appropriately (Drummond, 2018; Krening et al., 2012; Page et al., 2017). At a particular community hospital, lack of education and knowledge of the pharmacokinetics of Pitocin has led to inappropriate use of the titration protocol and, therefore, to ineffective and unsafe labor augmentation at this facility (M. Foster, personal communication, August 15, 2017), which mirrors Holmgren et al.’s (2011) and Miller’s (2015) findings. This is expected to continue unless comprehensive staff education is implemented to improve understanding of the mechanism of action of Pitocin and a checklist is implemented to guide future use of the Pitocin titration protocol in place in this unit (Drummond, 2018; Mahlmeister, 2008; Sundin, Mazac, Ellis, & Garbo, 2018).

**Background and Significance**

In 2007, the addition of oxytocin to the ISMP’s list of high-alert medications sparked much controversy over the safest practices for the administration of oxytocin (Mahlmeister, 2008). According to Doyle et al. (2011), misuse of Pitocin is one of the top five causes of
preventable perinatal harm and is frequently the subject of obstetrical medical liability cases (Drummond, 2018; Krening et al., 2012, Mahlmeister, 2008; Miller, 2015; Page et al., 2017). Clark et al. (2009) stated allegations of inappropriate Pitocin use account for half of all paid obstetric litigation claims. For this reason, many hospitals today employ the use of titration protocols for Pitocin administration in laboring patients (Rohn, Bastek, Sammel, Wang, & Srinivas, 2015). Despite evidence-based knowledge leading to the development of such protocols, the actual implementation of and adherence to such protocols remains a challenge in clinical practice (Arora et al., 2016; Holmgren et al., 2011).

Oxytocin is a neuropeptide hormone synthesized in the hypothalamus and secreted by the posterior pituitary gland. Oxytocin is also synthesized and secreted by the lining of the uterus, corpus luteum (located in the ovary), amnion (the membrane covering an embryo), and placenta (Arrowsmith & Wray, 2014). In the early 1900s, Dale identified the effect of oxytocin on the uterus, and in the early 1950s, a synthetic form of oxytocin was developed (Arrowsmith & Wray, 2014; Drummond, 2018; Page et al., 2017). Experimental use of synthetic oxytocin (Pitocin) by obstetricians began in the 1960s and 1970s, and by the 1980s, FDA approval had catalyzed its widespread use for labor induction and augmentation (Page et al., 2017). The chemical structure of Pitocin is identical to that of its endogenous counterpart; however, its effects on uterine contractions are not. Endogenous oxytocin is regulated with a feedback cycle and upregulation of receptor sites on the uterus; exogenous oxytocin is regulated by human titration independent of receptor site feedback cycles (Arrowsmith & Wray, 2014; Page et al., 2017; Sakala, Romano, & Buckley, 2016). The onset of action of Pitocin is 3–5 minutes, the half-life is 10–12 minutes, and the time to reach steady state is 40 minutes (Clark et al., 2009; Drummond, 2018; Mahlmeister, 2008; Page et al., 2017).
The most commonly associated adverse effects from misuse of Pitocin are nonreassuring fetal heart rate (FHR) patterns and failure to recognize and appropriately treat uterine tachysystole (the presence of more than five contractions in a 10-minute period, averaged over 30 minutes; Doyle et al., 2011; Drummond, 2018; Martin, Holder, & Rios, 2013; Page et al., 2017). Other associated effects of misuse of Pitocin include prolonged labor, increased risk of cesarean delivery, fetal acidemia, low Apgar scores, postpartum hemorrhage, uterine rupture, and even maternal and fetal death (Sakala et al., 2016; Wojnar et al., 2014).

**Purpose of the Project**

The purpose of this project was to increase staff adherence to the evidence-based Pitocin titration protocols in place at a community hospital labor and delivery unit. This should result in a decrease in adverse outcomes while improving the delivery of safe patient care. Based on available studies, if staff adherence to the protocol increases, a decrease can be expected in the following: maximum Pitocin rate used, length of labor augmentation, rates of cesarean delivery for fetal distress or failure to progress, uterine rupture, incidence of low Apgar scores, incidence of tachysystole, and postpartum hemorrhage (Krening et al., 2012; Martin et al., 2013; Rohn et al., 2015; Sundin et al., 2018; Wojnar et al., 2014).

**Nature of the Project**

In the project, I provided a 30-minute educational lecture to staff to increase their knowledge of the pharmacokinetics of Pitocin. Staff received a pretest and posttest based on material presented during the educational lecture. I introduced a checklist tool at the end of the lecture to guide decision-making when administering Pitocin for labor augmentation. I conducted chart audits to include six months preintervention and three months postintervention. I collected the following data: maximum Pitocin rate used, length of labor augmentation, presence of
meconium-stained fluid, rate of primary cesarean delivery for failure to progress or fetal distress, rate of spontaneous vaginal delivery and operative vaginal delivery, incidence of category II or category III FHR tracings, Apgar scores at 1 and 5 minutes of life, incidence of postpartum hemorrhage, incidence of uterine rupture, incidence of placental abruption, incidence of chorioamnionitis, and whether or not conditions met protocol guidelines upon initiation of Pitocin infusion and each time the Pitocin rate increased.

**Question Guiding the Inquiry**

I developed the research question using the population, intervention, comparative intervention, outcomes, and time (PICOT) method: For all term, singleton gestation labors using Pitocin for augmentation, does the education of the labor and delivery staff (P) on the pharmacokinetics of Pitocin and the implementation of a checklist tool (I) result in increased adherence to protocols (O) in the three months after intervention (T) compared to the six months prior to intervention (C)?

**Hypothesis**

On the labor and delivery unit of a community hospital, managers observed that staff did not routinely follow the Pitocin titration protocol. The management team hypothesized that lack of adherence to the evidence-based protocols stemmed from lack of understanding of the pharmacokinetics of Pitocin, lack of knowledge of the evidence behind the protocols, and lack of understanding of the assessment criteria in the protocol. The hypothetical question to be answered for this project was, Will comprehensive education of Pitocin and the Pitocin titration protocol, coupled with the implementation of a checklist tool, increase staff adherence to the Pitocin titration protocol?
**Conceptual Framework**

Application of evidence-based practice with outcomes evaluation is often approached from a quality improvement aspect. Therefore, the best framework for the project is a framework for quality improvement. Donabedian’s (2005) quality of care framework was selected for this project because it employs the use of three measures to guide a quality improvement project: structure, process, and outcomes (see Figure 1).

![Figure 1. A flowchart illustrating Donabedian’s quality of care framework. Adapted from “Conceptual Frameworks and Their Application to Evaluating Care Coordination Interventions,” by McDonald et al., 2007, in K. G. Shojania, K. M. McDonald, R. M. Wachter, & D. K. Owens (Eds.), Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies. Vol. 7: Care Coordination (Rockville, MD: Agency for Healthcare Research and Quality), p. 113. In the public domain.]

Structure measures, also known as input measures, reflect the ability to deliver the designated care. Structure measures may include variables such as staffing or availability of supplies. Process measures reflect how the process works to achieve the outcome. Outcome measures determine if the project resulted in the desired aim and reflect the impact of the project (Donabedian, 2005). During the planning stage of this quality improvement project, there was consideration for the structure and process measures that would most benefit the successful implementation of the project. Process measures interplay with the structure measures to
improve the likelihood of success. The project design needs to use process measures that will mitigate the limitations imposed by the structure measures (Donabedian, 2005).

Because the success of this type of improvement project relies heavily on staff compliance, it is prudent to incorporate a framework to guide the specific process involved—staff education. Professional nurses are adult learners; an improvement project involving alteration in behavior necessitated effective techniques to encourage and motivate the adult learner to invest in the initiative (M. Knowles, Holton, & Swanson, 2015). For this reason, the development of process measures incorporated Knowles’s adult learning theory to ensure the effectiveness of the project design. There are six principles to the theory of adult learning:

1. The need to know: Adults need to know why they need to learn something before undertaking to learning it.

2. The learners’ self-concept: Adults have a self-concept of being responsible for their own decisions. . . . They resent and resist situations in which they feel others are imposing their wills on them.

3. The role of the learners’ experiences: Adults come into an educational activity with both a greater volume and a different quality of experience from that of youths. . . . The richest resources for learning reside in the adult learners themselves.

4. Readiness to learn: Adults become ready to learn those things they need to know and be able to do in order to cope effectively with their real-life situations.

5. Orientation to learning: Adults are motivated to learn to the extent that they perceive that learning will help them perform tasks or deal with problems that they confront in their life situations.
6. Motivation to learn: The most potent motivators are internal pressures (the desire for increased job satisfaction, self-esteem, quality of life, and the like). (M. Knowles et al., 2015, pp. 64–68)

**Operational Definitions**

The following terms guided the data collection and assessment.

**Apgar score.** An assessment of newborn well-being at 1, 5, and 10 minutes of life. Points of 0, 1, or 2 are given for five categories: appearance, pulse, grimace, activity, and respiration (Cunningham et al., 2018).

**Labor.** The presence of regular uterine contractions that cause cervical dilation or effacement (Cunningham et al., 2018).

**Low Apgar score.** An Apgar score of less than 3 at five minutes of life (Cunningham et al., 2018).

**Nonreassuring fetal status.** A persistent decrease in fetal heart tone variability or the presence of recurrent or prolonged decelerations in the FHR, classified as a category II or category III FHR tracing (Gravett et al., 2016).

**Pitocin augmentation.** Any labor with the use of Pitocin to enhance the strength or frequency of spontaneously occurring labor contractions (Cunningham et al., 2018).

**Pitocin induction.** Any labor in which Pitocin is used for the initiation of contractions (Cunningham et al., 2018).

**Postpartum hemorrhage.** Blood loss of more than 500 ml for a vaginal delivery or more than 1,000 ml for a cesarean delivery (Cunningham et al., 2018). (This definition has changed since the beginning of this project. However, I retained the previous definition for this project as that was how this facility defined postpartum hemorrhage during the project time.)
Singleton pregnancy. A pregnancy with one fetus (Cunningham et al., 2018).

Tachysystole. More than five contractions in 10 minutes, averaged over 30 minutes (Cunningham et al., 2018).

Term gestation. Any pregnancy that is 37 0/7 weeks to 41 6/7 weeks (Cunningham et al., 2018).

Uncomplicated pregnancy. A pregnancy with a normal course with no health risks to mother or fetus and no presence of high-risk factors, such as gestational diabetes, pregnancy-induced hypertension, or fetal anomalies (Cunningham et al., 2018).

Scope and Limitations

The project included all the nursing staff in the labor and delivery unit at a community hospital. Also, all obstetrical providers with privileges to deliver patients at the facility received notification of the project. Inclusion criteria for charts audited were Pitocin use for augmentation and uncomplicated, term, singleton gestation. Exclusion criteria were any delivery occurring spontaneously without the use of Pitocin, labor induced with Pitocin, multiple gestation, pre- or postterm gestation, and pregnancies complicated with comorbidities, such as gestational diabetes, pregnancy-induced hypertension, poly- or oligohydramnios, fetal anomalies, maternal obesity, cholestasis of pregnancy, or maternal infection other than chorioamnionitis. Constraints to the project were obstetrical provider support and buy-in and a recent influx of new staff who were not present when the initial implementation of the protocol took place.

Summary

The use of Pitocin is pervasive and unavoidable in obstetrics. There is a fine line between appropriate use of Pitocin and misuse that can cause significant harm or death to both the mother and the fetus (Clark et al., 2009; Holmgren et al., 2011; Krening et al., 2012; Mahlmeister, 2008;
Sundin et al., 2018; Wojnar et al., 2014). Misuse of Pitocin is among the top causes of preventable perinatal harm and is a common theme in litigation (Clark et al., 2009; Doyle et al., 2011; Page et al., 2017). Studies have shown significant improvements in outcomes with the implementation of Pitocin titration protocols (Krening et al., 2012; Martin et al., 2013; Rohn et al., 2015; Sundin et al., 2018; Wojnar et al., 2014). Staff adherence is paramount to the successful implementation of evidence-based titration protocols and may be improved with the use of adult learning techniques (Drummond, 2018; Holmgren et al., 2011; Krening et al., 2012; Mahlmeister, 2008; Sundin et al., 2018).
Chapter 2: Literature Review

In 2007, the ISMP acknowledged the potential dangers of Pitocin (oxytocin) when used inappropriately (ISMP, 2014). Since the ISMP’s placement of Pitocin on the high-alert medications list, the medical community has acknowledged and evaluated the safety of its use in the obstetrical setting and has established the use of titration protocols to minimize risk when administering Pitocin (Clark et al., 2009; Doyle et al., 2011; Krening et al., 2012; Rohn et al., 2015).

At a community hospital labor and delivery unit, management observed that implementation of a Pitocin titration protocol did not result in a satisfactory level of nursing staff compliance (M. Foster, personal communication, August 15, 2017). Successful implementation of evidence-based guidelines in the clinical setting can be difficult, and the process of developing successful implementation strategies merits attention (Holmgren et al., 2011). The management team hypothesized the lack of adherence to the evidence-based Pitocin titration protocol stemmed from a lack of understanding of the pharmacokinetics of Pitocin, the evidence on which the protocol is based, and a lack of understanding of the assessment criteria in the protocol (Miller, 2015). Based on this information, I developed the research question for this study: For all term, singleton gestation labors using Pitocin for augmentation, does the education of the labor and delivery staff on the pharmacokinetics of Pitocin and the implementation of a checklist tool result in increased adherence to protocols in the three months after intervention compared to the six months before intervention?

The review of relevant literature for this study revealed a large, ongoing discussion and debate regarding the proper use of Pitocin. The literature review therefore focused on the discussion of Pitocin used for augmentation. While several studies have been done to evaluate
the effectiveness of Pitocin protocols in increasing patient safety, only a small number of these studies addressed the necessity of proper staff education to ensure adherence to such protocols. All studies addressed to some extent the change in outcomes following protocol implementation. Also included in the literature review was research related to educational implementation methods for protocols in other clinical settings.

**Literature Search Methods**

I conducted a literature search using CINAHL complete, Science Direct, Academic Search Complete, Science and Technology Collection, and Google Scholar. Articles found and reviewed were limited to English peer-reviewed scholarly journals between 2005 and 2018 with full text available. This search produced 3,104 articles, which I narrowed down to 97 articles relevant to the topic and further narrowed down to 26 articles specifically addressing the topic of Pitocin.

**The Need for a Pitocin Protocol**

Several recent studies have reviewed the literature on Pitocin. Drummond (2018) gave an overview of the history of Pitocin use, from its discovery in 1909 and synthesis in 1954 to its widespread use today in up to 50% of laboring women. Drummond discussed recommended indications for use in labor and suggested dosing regimens, as well as assessment guidelines. Drummond concluded that for the safe use of Pitocin, each facility should develop uniform guidelines and employ a checklist while Pitocin is in use to guide the titration.

Kernberg and Caughey (2017) reviewed literature specifically discussing Pitocin augmentation and active management of labor. The authors discussed the use of Pitocin for augmentation from its origins in the 1960s, and briefly reviewed the studies conducted through 2016. They found that the methods and suggested protocols for Pitocin administration have
evolved over the years, with initial trials aimed at speeding the labor process and reducing cesarean delivery rates. It was not until 2007 that a retrospective review considered the effects of Pitocin use on maternal and fetal well-being and suggested a closer examination of the risks of using Pitocin (Kernberg & Caughey). Subsequent studies have focused more on in-use checklists and protocols and evaluating the effects on fetal and maternal outcomes. For example, the American College of Obstetricians and Gynecologists (ACOG, 2009) recommended that each facility have administrative guidelines for Pitocin usage. Kernberg and Caughey identified the pervasive theme throughout the literature from the 1960s to the present as a wide range of recommended protocols, with no clear evidence as to which protocol is best but that the use of a standard protocol is necessary for patient safety. Kernberg and Caughey concluded that the standardized use of Pitocin is a necessity in the current patient safety culture and further studies are needed to develop a truly standardized protocol that promotes patient safety and improved outcomes.

Page et al.’s (2017) review of current literature discussed the pharmacology of Pitocin and guidelines for its use in labor. The authors discussed the physiologic effects of Pitocin in detail, pointing to the need for a protocol to guide the safe use of Pitocin for induction or augmentation of labor. Page et al. advised developing a standard order set that takes into consideration the pharmacokinetic properties of Pitocin and a checklist to guide the initiation and administration during labor.

Arora et al. (2016) also discussed the use of quality improvement tools to improve safety and outcomes. They noted that evidence has shown the effectiveness of using protocols and checklists that are “(1) evidence-based and can facilitate measurable improvements in quality of care, (2) aid timely diagnosis and treatment to prevent or limit the severity of morbidity, and (3)
are customizable for local implementation” (Arora et al., 2016, p. 445). The authors also noted the implementation of these tools correlated to a decrease in litigation costs and adverse outcomes. Arora et al. asserted that need for protocols in acute care had been well demonstrated, but that poor compliance has prevented the successful implementation of these tools.

Oláh and Steer (2015) discussed the implications of the use and misuse of Pitocin. The authors outlined the history of Pitocin discovery, mechanism of action, and implications for use in labor. In their review of relevant literature, Oláh and Steer revealed inconsistent findings with the efficacy of Pitocin use for augmentation of labor. They noted, however, was that the misuse of Pitocin was a common reference in obstetrical litigation. The most common errors were initiating or continuing the use of Pitocin when FHR tracings indicated a level of fetal compromise. Oláh and Steer noted that recognizing this prevalent theme in malpractice cases had triggered the development and use of checklists and standardized infusion protocols to mitigate the misuse of Pitocin.

In a clinical opinion, Clark et al. (2009) analyzed recent evidence of the mechanism of action of oxytocin and the effects of its use clinically. The authors concluded from the analysis of the current data that the use of a standardized protocol with a focus on uterine and fetal response and consideration for the known pharmacokinetic properties of the drug should accompany oxytocin administration (Clark et al., 2009). Similarly, Mahlmeister (2008) summarized a literature review of the pharmacokinetics of Pitocin and the evidence-based titration protocol. Of note, some physicians have utilized protocols designed for specific patient types on inappropriate patients, resulting in poor outcomes (Mahlmeister, 2008). Therefore, it is important that institutions develop appropriate protocols based on the current evidence, with staff properly educated in the use of protocols.
The inappropriate use of oxytocin is among the top five causes of preventable perinatal harm (Doyle et al., 2011). Implementing an evidence-based, standardized protocol for oxytocin use can decrease instances of perinatal harm (Doyle et al., 2011). Similarly, Krening et al. (2012) noted oxytocin-induced tachysystole is responsible for a large number of obstetrical liability claims with patient safety, necessitating a standardized, evidence-based protocol and process. Mahlmeister (2008) cited mismanagement of Pitocin as a recurrent theme in obstetrical lawsuits and asserted safe practice demands uniform evidence-based protocols on high-reliability units. Rohn et al. (2015) triggered the recognition that the safety and quality of obstetric care have been addressed with the use of standardized Pitocin protocols, citing better outcomes and decreased legal liability. Wojnar et al. (2014) similarly recognized the potential for significant patient harm when mistakes in Pitocin administration occur and pointed out the benefit of checklist usage to prevent harm previously established in the health care field.

Smith, Zacharias, Lucas, Warrick, and Hamilton (2014) revealed the incidence of uterine tachysystole associated with Pitocin use, citing tachysystole as a commonly used measure to evaluate compliance with Pitocin titration protocols. In this study, uterine tachysystole was a common finding but only rarely led to adverse neonatal or maternal outcomes. Smith et al. also noted no significant difference in rates of tachysystole between the women who received Pitocin and the women who did not. Smith et al. recommended that Pitocin titration protocols not be based solely on the contraction pattern but also on the FHR response to contractions.

In a synthesis of a larger report, Sakala et al. (2016) discussed the hormonal physiology of pregnancy and labor and the associated effects of artificial and external forces. Endogenous oxytocin release during labor is described as pulsatile and episodic, effectively manipulating receptor sensitivity and controlling the strength and effectiveness of contractions. While
synthetic oxytocin (Pitocin) is chemically identical to oxytocin produced endogenously, the intravenous administration resulted in different clinical effects. Among these effects was receptor desensitization, which led to an increased risk of postpartum hemorrhage and fetal hypoxia. Sakala et al. noted the classification of Pitocin as a high-alert medication and recommended the avoidance of Pitocin unless necessary.

Likewise, Arrowsmith and Wray (2014) discussed the pharmacokinetics of Pitocin at length, highlighting the complexity of its origins and effects. The authors identified two aspects to describe how Pitocin regulates labor: the concentration of Pitocin in the bloodstream and the sensitivity of Pitocin receptor sites. Arrowsmith and Wray also mentioned that the prolonged exposure to Pitocin resulted in a decrease in the responsiveness of receptor sites and eventually a decrease in the number of receptor sites, which can lead to ineffective labor contractions, uterine atony, and postpartum hemorrhage. Pitocin infusion can also cause hyperstimulation of the uterine muscle, resulting in fetal hypoxia due to decreased blood flow. While recommendations in the literature were to infuse Pitocin with the guidance of a titration protocol, there was no agreement on the best combination of dosage, rate, and frequency of titration (Arrowsmith & Wray, 2014).

**Effectiveness of Current Protocols**

Sundin et al. (2018) recently published a quality improvement project evaluating clinical outcomes after implementation of a Pitocin checklist. Sundin et al. used a quality group to evaluate the current literature and to develop a checklist for the administration of Pitocin. The project group implemented the checklist on singleton (single intrauterine pregnancy), vertex, term pregnancies. The group reviewed 200 charts before the intervention, as well as 200 charts after the intervention. The project group noted a significant decrease in overall cesarean birth
rate, the cesarean birth rate for FHR abnormalities, tachysystole, total Pitocin time, maximum Pitocin dose, and the number of times Pitocin was discontinued or decreased. The total length of labor did not decrease significantly, and the rate of chorioamnionitis was unchanged (Sundin et al., 2018).

Rohn et al. (2015) evaluated the use of Pitocin protocols for labor augmentation. While there was an adequate amount of research suggesting the use of protocols was associated with better outcomes, there was only one small trial that evaluated outcomes pre- and postprotocol implementation. The retrospective cohort study included deliveries from two 15-month periods: preimplementation of a Pitocin protocol and postimplementation of this protocol, with a 9-month transition period in between. Rohn et al. found significant increases in rates of chorioamnionitis, cesarean delivery for labor dystocia, length of time from admission to delivery, and length of time from rupture of membranes to delivery; a decrease in rates of cesarean for fetal distress; and a decrease in maximum Pitocin rate used. A limitation of the study was that an additional low-dose Pitocin regimen was implemented at the same time as the checklist intervention, so it was unclear if the new regimen influenced some of the outcomes (Rohn et al., 2015). Also, while the rates of chorioamnionitis were significantly increased in the first six months postintervention, the following 9 months showed a decrease, indicating that the staff possibly became more competent in the use of the protocol over time (Rohn et al., 2015).

Clay-Williams and Colligan (2015) discussed the use of checklists in health care as a safety measure, with checklists being useful for normal or complicated situations but perhaps not complex situations. Following the implementation of a surgical safety checklist, mixed results indicated that initiation of a checklist alone was not an adequate intervention and that training, teamwork, and leadership were important steps in the process (Clay-Williams & Colligan, 2015).
Martin et al. (2013) assessed the effectiveness of a revised Pitocin protocol that provided for stricter adherence to surveillance and documentation. The researchers evaluated effectiveness by measuring the incidence of tachysystole before and after the intervention, as well as tachysystole-related adverse neonatal outcomes and compliance with the protocol. Postintervention compliance improved from 25.9% to 97.8%. The incidence of tachysystole was 10.83%, with adverse neonatal outcomes at 3.49%; the significance of this decrease was unreported (Martin et al., 2013).

Krening et al. (2012) evaluated a process improvement intervention for a Pitocin titration protocol. Staff education occurred based on the most recent evidence and the newly implemented policy. Krening et al. collected data from pre- and postintervention, comparing average length of labor, duration of oxytocin use, rate of tachysystole, primary cesarean delivery rate, and overall cesarean delivery rate. The researchers found a significant decrease in the average length of oxytocin use, which extrapolated to a $173,000 annual savings to the health care system. The incidence of tachysystole was also significantly decreased. The rates of primary and overall cesarean delivery decreased (Krening et al., 2012); however, the authors did not state if this decrease was statistically significant.

In contrast to Krening et al. (2012), Somprasit, Tanprasertkul, and Kamudhamas (2005) identified a decrease in length of labor for a group of women with an active management protocol that included a Pitocin titration protocol, as compared to a group of women in a conventional management of labor group with no guidelines for the use of Pitocin. While there was a decreased trend in the rate of cesarean delivery, the decrease was not found to be statistically significant (Somprasit et al., 2005).
Staff Education and Adherence to Protocols

In a quality improvement project, Sundin et al. (2018) used a study design that included nurse education of current evidence-based practice for Pitocin titration. Education included an in-depth explanation of a checklist for Pitocin use and the expected documentation. Key elements of the study design conducive to the success of the project included support from the chief obstetrical provider and time spent on nurse education. Sundin et al. asserted implementation must occur with education and a positive safety culture to be successful.

Miller (2015) discussed the use of a tachysystole protocol to mitigate risks of excessive uterine activity during labor. Miller noted these policies and protocols “are only effective in the hands of educated clinicians capable of critical thinking,” and educational intervention when implementing protocols was important to bolster critical thinking for protocol and checklist use (p. 8).

Martin et al. (2013) used protocol revision and staff reeducation to increase compliance with protocols. A tachysystole management protocol was added to complement the oxytocin safety flowsheet. Martin et al. noted that education occurs with both physicians and nurses. When staff education coincided with the implementation of the new protocol, Martin et al. noted a compliance increase from 25.9% to 97.8% from 2008 to 2012. Since the conclusion of the study, compliance with the protocol remained at 91.3% (Martin et al., 2013).

Doyle et al. (2011) used yet another educational approach for the implementation of a new protocol. Each staff nurse participated in a 30-minute mandatory in-service, with examples of what to do and how to follow the protocol in instances of tachysystole or if a provider is resistant to following the protocol. Monthly, a team audited 20 charts for the presence of tachysystole and protocol adherence. If a nurse was found to be habitually noncompliant, that
nurse was counseled and reeducated on the protocol. The team recognized nurses who demonstrated excellent records in avoidance or proper treatment of tachysystole. The process of continuous auditing and reeducation was influential in increasing compliance with the protocol (Doyle et al., 2011).

Wagner et al. (2011) evaluated the slow change in the implementation of patient safety initiatives in obstetrics. The study included the implementation of many quality improvement initiatives, with extensive staff education for each measure and continuous monitoring of understanding throughout the implementation process. Among other things, Wagner et al. found improved compliance with the Pitocin augmentation protocol. Implications for practice included fostering a team approach and better communication, with success dependent on the ability to constantly monitor the impact of the intervention (Wagner et al., 2011).

Mandel et al. (2009) documented another interesting approach. At a Magnet organization, Mandel et al. used a collaborative process to create and implement a Pitocin protocol. All disciplines were involved in the research and development process, including staff nurses, midwives, and physicians. This process allowed for everyone to be invested in the project and, therefore, be invested in its success. A chart audit after implementation of the new protocol found 87.5% physician compliance and 90.0% nurse compliance (Mandel et al., 2009).

Mahlmeister (2008) posited the first step in implementing a protocol for oxytocin use was staff education. In alignment with this suggestion, Holmgren et al. (2011) evaluated the use of Pitocin titration protocols and compliance with such protocols. Holmgren et al. cited literature that showed effective implementation strategies must be used to increase staff compliance with guidelines and protocols. In this study, Holmgren et al. used a multifaceted approach to address two identified barriers to change. The implementation process involved an education measure,
audits with feedback, and a core group of staff that served as champions for the change. Holmgren et al. attributed the success of implementation to the combination of these methods. The evaluation six months posteducation showed a statistically significant increase in the appropriate use of the protocol, as well as documentation for oxytocin augmentation. Holmgren et al. also noted that allowing staff to express concerns with the new process was an important factor with compliance.

**Clinical Education Methods**

In a quality improvement project, Marino, Bucher, Beach, Yegneswaran, and Cooper (2015) used formal didactic education coupled with supplemental print materials and a screening tool to implement a new protocol for prevention and management of delirium in adult ICU patients. Marino et al. offered the intervention to critical care nurses on three ICU units and used a knowledge assessment survey to evaluate the educational intervention. The researchers offered the intervention eight times over 2 weeks, with each session lasting 1 hour. After this period, Marino et al. allowed 4 weeks for those not participating in the didactic education to utilize the print materials for self-teaching. Implementation of the screening tool and protocol occurred 4 weeks after the last formal didactic education offering. Approximately one-third of the nursing staff participated in the intervention, which resulted in a 56.3% compliance with the new protocol across the three units. When analyzed by individual unit, one unit had an 82.4% compliance rate, while the other two showed compliance at 53.0% and 34.6%. Participation was not broken down by unit, so Marino et al. did not report a correlation between participation and compliance. Of the nurses who participated in the formal didactic portion of the intervention, there was a statistically significant increase in knowledge of the subject postintervention (Marino et al., 2015).
In a descriptive study, S. Knowles et al. (2015) reviewed the effects of an implementation model for a bowel management protocol on three ICU units. The authors posited that adherence to protocols would be higher if the protocol was implemented with evidence-based strategies rather than by itself. Evidence-based implementation strategies included “education, audit and feedback, reminders, mass media, and use of local opinion leaders” (S. Knowles et al., 2015, p. 2). After the implementation of the protocol, a statistically significant improvement in knowledge of the subject matter was appreciated. However, there was no statistically significant increase in the use of the protocol. S. Knowles et al. concluded factors other than knowledge influence adherence and that people respond differently to different implementation strategies.

Yost et al. (2015) led a systematic review to determine if knowledge translation interventions were effective, if they affected patient outcomes, and what factors influenced the effect of these interventions. The authors defined knowledge translation as any intervention that involved translating evidence into practice. Yost et al. found most interventions performed included several methods. Single-method interventions involved educational meetings, materials, and a clinical decision support system. All but one study included an educational aspect to the intervention. The literature supported small to moderate improvements with educational methods, and didactic education was less effective than interactive education. Factors contributing to a successful intervention included “positive interpersonal relationships, supportive environment, shared governance and leadership, ability to engage staff nurses at different junctions and to overcome negative reactions to practice changes, and allocation of resources and administrative support” (Yost et al., 2015, p. 11). Another prevalent theme in the literature was the context in which the education took place, with a positive environment
contributing to successful intervention. Recommendations by Yost et al. (2015) included the use of education in the intervention and involvement of leadership in the implementation process.

In a descriptive qualitative study, Govranos and Newton (2014) evaluated the factors influencing staff nurses’ continuing education. The authors conducted focus group interviews with 50 full-time staff nurses on a medical-surgical unit regarding their perceptions and values toward education. Govranos and Newton concluded that staff nurses perceived continuing education to be important and that it was important for educators to recognize the needs of an adult learner. Interviews with nurses indicated they preferred learning to occur in the workplace, with a culture of learning based on adult learner needs as an important element to the effectiveness of education. Govranos and Newton pointed out that adults are motivated to learn when they need to know the information, and both the learner’s learning style and the teacher’s teaching style influence effective learning.

Summary

It is evident from the literature that the use of a protocol for the titration of Pitocin is considered best practice (Arora et al., 2016; Clark et al., 2009; Doyle et al., 2011; Drummond, 2018; Kernberg & Caughey, 2017; Krening et al., 2012; Oláh & Steer, 2015; Page et al., 2017; Rohn et al., 2015; Wojnar et al., 2014). The recommendations included guidelines for initiation and continuation of Pitocin infusions, including avoidance of tachysystole (Doyle et al., 2011; Kernberg & Caughey, 2017; Krening et al., 2012; Mahlmeister, 2008; Martin et al., 2013; Sundin et al., 2018; Wagner et al., 2011). In addition to the implementation of titration protocols, it is paramount the nursing staff receive effective education regarding the basis for and proper use of the protocol (Govranos & Newton, 2014; Yost et al., 2015). These studies showed that with effective staff education and follow-up, the use of Pitocin titration protocols increased patient
safety by decreasing the incidence of tachysystole and related adverse events (Doyle et al., 2011; Holmgren et al., 2011; Mahlmeister, 2008; Mandel et al., 2009; Martin et al., 2013; Sundin et al., 2018; Wagner et al., 2011).
Chapter 3: Research Method

This project was designed to improve adherence to the Pitocin titration protocol in a labor and delivery unit at a U.S. community hospital. I specifically implemented an interventional project with a quality improvement design that was tailored toward adult learners. The project was guided by Donabedian’s (2005) quality of care framework and Knowles’s adult learning theory (M. Knowles et al., 2015). The project’s success was measured using statistical analysis to compare chart data for adherence to protocol and trends in pre- and postintervention patient outcomes.

Project Design

This quality improvement project consisted of three steps: preintervention data collection, educational intervention, and postintervention data collection. Preintervention data collection consisted of gathering data collected from the prior six months’ charts using a chart audit template (see Appendix A). The intervention consisted of a 30-minute educational lecture covering the pharmacokinetics of Pitocin and a review of the evidence on which the Pitocin titration protocol is based (see Appendix B). I introduced a checklist tool to assist with the proper use of the protocol. Administration of a pretest and posttest assessed the effectiveness of the intervention on understanding of the protocol (see Appendix C). I collected data from chart audits for three months postintervention.

Structure measures. This project was guided by Donabedian’s (2005) quality of care framework, which states that structure measures are the factors of the environment that affect the care delivered or the implementation of the project. The structure measures of this project were the labor and delivery staff who received the intervention, the physicians who were involved in the patient care, the staffing and acuity of the labor and delivery unit for each shift, and the
chosen method of intervention for the project. The percentage of the staff who attended the educational lecture influenced the effectiveness of the project. The support and buy-in of the physicians who guided the care of each patient also influenced the effectiveness of project implementation. When the unit was very busy and understaffed, this factored into how committed the staff was to follow the guidelines implemented by the project.

The chosen method of intervention affects how successful a project is. Knowles’s (M. Knowles et al., 2015) adult learning theory was therefore chosen to guide this aspect of the project. According to this theory, adult learners are motivated to learn when the subject matter pertains to their work, when they will receive a benefit from learning, and when the information they are learning will solve a problem. Therefore, the information that adult learners learn should build on what they already know and should consist of information they need to know (M. Knowles et al., 2015). Using these guidelines, the educational lecture was designed to provide information on the known adverse effects of inappropriate Pitocin use and how this directly affected leaners’ jobs, their patients’ safety and outcomes, and their organization. The intervention incorporated the existing Pitocin titration protocol that the staff were already familiar with and highlighted the evidence that was the basis for each component of the protocol. The intervention also illuminated the expected positive outcomes from the appropriate use of the titration protocol based on documented studies.

**Process measures.** Donabedian’s (2005) process measures were components of the project that were aligned to help achieve the desired outcome. The process measures for this project were the chosen interventions: an educational lecture and the use of a checklist tool as a charting reminder. The educational lecture provided the information needed for the staff to understand better the Pitocin titration protocol and the evidence-based pharmacologic properties
of Pitocin. Guided by the adult learning theory, this educational lecture provided the why for adherence to the titration protocol. The lecture was offered five times over 1 month in a reserved classroom in the unit where the project took place, providing multiple opportunities for all staff to participate or to attend more than once, if desired.

The checklist tool was posted on every computer screen the labor and delivery staff used for charting and on every IV pump used to titrate Pitocin (see Appendix D). The checklist tool served as a reminder to follow the protocol each time a nurse was going to use the pump to increase the Pitocin rate or to chart in the electronic health record an increase in the Pitocin rate.

**Outcome measures.** Outcome measures are factors identified to highlight how successful the project was in achieving its goals (Donabedian, 2005). Outcome measures for this project consisted of the data collection and analysis from chart audits. Based on evidence from the literature review, the expectation was for the intervention to result in improved adherence to the Pitocin titration protocol. If achieved, improved adherence should have resulted in a decrease in the average maximum Pitocin rate used for augmentation, the length of labor augmentation, the rate of primary cesarean delivery for failure to progress or nonreassuring fetal status, operative vaginal delivery, the incidence of tachysystole, category II or category III FHR tracing, postpartum hemorrhage, uterine rupture, and an increase in Apgar scores at 1 and 5 minutes (Doyle et al., 2011; Holmgren et al., 2011; Mahlmeister, 2008; Mandel et al., 2009; Martin et al., 2013; Sundin et al., 2018; Wagner et al., 2011).

**Balancing measures.** Donabedian (2005) described balancing measures as those unintended consequences of the intervention, either good or bad. Unintended consequences could have been an improvement in patient outcomes for unexpected measures or unintended negative effects, such as an increase in chorioamnionitis (an infection of the fetal membranes).
resulting in longer hospital stays for the newborn. Balancing measures were unknown until project implementation was complete and postintervention data were collected and assessed.

**Measurement Tool**

To measure intervention success, I used statistical analysis of descriptive data collected from chart audits, with a predesigned chart audit form (see Appendix A). As I was the only person who collected data, it eliminated issues with interrater reliability (Vassar & Holzmann, 2013). I evaluated the effectiveness of the educational lecture using a pretest and posttest I designed to reflect the content of the educational intervention (see Appendix C). A one-sample t test assessed for a statistically significant improvement in posttest scores.

**Data Management**

**Data collection.** The director of women’s services at the hospital gave permission for data collection. Additionally, I obtained a letter of support from the hospital’s chief nursing officer to conduct the project at this facility (see Appendix E).

I used the unit delivery log (the logbook that documents every interfacility delivery) to create a preliminary list of charts for inclusion in the project based on those identified as augmented labors. I deidentified all demographic data by only including medical record numbers to identify charts for auditing. Identified charts underwent an audit and the collected data written on the chart audit form. I further deidentified data with the use of a sequential numbering system in place of the medical record number upon transfer from the paper form to the electronic file.

**Data management.** All data collection was done on site by me, the principal investigator, and stored in a locked locker located in the unit where data collection occurred. I was the only person with access to this locker. I entered the deidentified data into an Excel spreadsheet and transferred the data to SPSS Version 26.0 for analysis.
Data analysis. I evaluated measurement of adherence by looking at each Pitocin rate increase and noting whether the protocol criteria were met based on documentation of contraction frequency, Montevideo units, and the category of fetal heart tracing. If any of these components did not meet the criteria for an increase in the Pitocin rate, I recorded an N on the chart audit form. If the criteria were met, I recorded a Y on the chart audit form. In an Excel spreadsheet, I built a table consisting of the number of Ns for each preintervention chart and each postintervention chart. SPSS provided statistical analysis of the data. I performed a chi-square analysis to determine if there was a statistically significant difference between the frequency of N before the intervention and the frequency of N after the intervention.

Supportive data analysis included an evaluation of the expected changes in patient outcomes. In Excel, I built a table to include pre- and postintervention data for the maximum Pitocin rates achieved, the total length of augmentation time, the frequency of category II and category III fetal heart tracing documented, 1-minute and 5-minute Apgar scores, and the overall pre- and postintervention frequency of postpartum hemorrhage, uterine rupture, placental abruption, primary cesarean delivery and operative vaginal delivery. I performed independent samples t test or chi-square analysis for each category to determine if a statistically significant difference existed.

Methodology Appropriateness

Data collection. The method of data collection afforded every possibility of confidentiality. There was only one investigator. I accessed charts based on the medical record number, and once accessed, no demographic data were recorded. Furthermore, data transcription from the chart audit sheet to the Excel spreadsheet was further deidentified by excluding the
medical record number and assigning sequential numbers to each record. Final data tables included no identifying patient information.

The identity of the nurse who documented on each chart remained confidential as well. The charting system used by the facility recorded only mnemonics for nurse identification. The principal investigator was unaware of the name of the nurse corresponding with each mnemonic, nor did the principal investigator record information relevant to the documenter on the chart audit sheet.

I kept chart audit sheets in a folder inside a locked locker in the unit where data collection took place. I was the only person with access to this locker, thereby eliminating the possibility of anyone else viewing the data. Data will be stored for three years and consent forms for six years following the completion of the study, per Institutional Review Board (IRB) requirements, and destroyed at the end of this time.

**Data analysis.** I analyzed the data set using an independent samples *t* test and chi-square analysis. A *t* test is the most efficient way to investigate the difference between two sets of data by comparing the mean values of the measurement variable (McDonald, 2014). The data for a *t* test must be continuous and numeric, with the observations being independent of each other. I evaluated the data that met criteria using the independent samples *t* test. A *p* value of 0.05 or less indicated a statistically significant difference in the mean values of the two data sets. Chi-square analysis compares observed counts with expected counts to determine statistical significance when the variable is nominal with two or more values. Data that met these criteria underwent chi-square analysis. If the expected count was too small, I used Fisher’s exact test instead (McDonald, 2014).
**Informed consent.** All nurses who participated provided informed consent prior to the planned intervention. A brief explanation of the project occurred at the unit staff meeting 1 week prior, and informed consent forms were provided. Time was allowed for review, and for those who chose to participate, consent forms were collected at the beginning of the educational intervention. If a nurse chose not to participate, charts from her patients were excluded from the preliminary audit list.

**Feasibility**

A clinical site agreement with the facility allowed me to conduct research in association with Abilene Christian University (ACU). The chief nursing officer of the facility provided a letter of support for the project (see Appendix E). Arrangements were made with the director of women’s services at the facility to conduct chart audits at my convenience in a designated location in the unit.

The only costs incurred were for printing and laminating of the checklist tool, with no other costs identified. Other constraints to the project included provider support and nurse participation. Provider support was encouraged through an invitation to the educational intervention. Nurse participation was expected to be high as the participation effort was minimal. However, some nurses were on vacation, on scheduled medical leave, or were unavailable to participate at any time of the intervention. To eliminate a potential confounder to the results due to lack of participation in the intervention, chart audits excluded charts noted in the delivery log to be associated with these nurses.

**IRB Approval and Process**

Research ethics and compliance training and protecting human research participants training occurred according to the requirements of the ACU IRB and the project site’s IRB
(PIRB). As the principal investigator, I filed credentials and financial conflict of interest disclosures, as required by the PIRB. I also submitted the project proposal, the consent form, and all educational materials to be used to the ACU IRB for approval before submission to the PIRB, in accordance with its internal requirements (see Appendix F).

**Interprofessional Collaboration**

The director of women’s services offered support of the project and any available resources needed. I invited all obstetrical providers with hospital privileges to participate in the project by attending the educational intervention. I stressed to all staff, both medical and nursing, that the protocol was a guideline and the provider would ultimately guide the patient’s care.

**Sample and Setting**

**Target population.** The target population was the entire labor and delivery nursing staff at a community hospital in central Texas. There were 25 full-time nurses and nine as-needed nurses employed in this unit. There were seven nurses over the age of 50, and 27 nurses were ages 24 to 49. There were seven nurses with more than 20 years of obstetrical nursing experience, 20 nurses who had 6–19 years of obstetrical nursing experience, and six nurses who had less than five years of obstetrical nursing experience. There were 11 nurses who were new to the organization, having been recently hired following the closing of a nearby hospital’s labor and delivery unit.

**Project setting.** The project took place in the labor and delivery unit of a community hospital. Evaluation of pregnant patients who are 20 weeks’ gestation or greater and delivery of laboring patients who are 27 weeks’ gestation or greater occurred in this unit. Historically, the unit logged 100–120 deliveries per month, with a recent influx of patients due to the closing of the labor and delivery unit at a neighboring hospital, which increased deliveries by 60% each.
month. The unit had an obstetric hospitalist in-house 24 hours a day available to evaluate all patients at the nurse’s or admitting physician’s request.

Recent turnover in the unit leadership shifted the focus toward a culture of education and quality process improvement. At the time that the project intervention began, the department director had been in her position for 1.5 years, whereas the clinical coordinator had been in her position for 1 year. New initiatives from the leadership team included monthly mandatory lectures given by the obstetrics hospitalist group on relevant obstetrical topics. There was also a newly formed, unit-specific Quality Assurance and Performance Improvement Committee that regularly implemented quality improvement projects.

**Risks and Benefits**

**Risks.** One potential risk of this project involved participants experiencing embarrassment at poor care performance related to using the protocol. This risk was minor, as the data collection did not involve identifiable data regarding participants. Nursing documentation included mnemonics only and was deidentified; the investigator did not have information linking participants with their mnemonic. Nurses were not singled out for documentation errors and were not asked to do anything outside of their scope of practice.

**Benefits.** Participation in the study was designed to generate several benefits. Potential benefits included increased knowledge and competency in the clinical specialty, increased understanding of the Pitocin titration policy and protocol, and increased awareness of the risks of Pitocin misuse. However, there was no guarantee of these benefits for each participant.

**Timeline**

Preintervention data collection began after receipt of IRB approval. Preintervention data was collected through chart audits of charts from May 1, 2018, through October 31, 2018. The
intervention occurred in November 2018. The postintervention data collection period started December 1, 2018, and continued through February 28, 2019 (see Appendix G for complete project timeline).

**Summary**

This quality improvement project was implemented on a labor and delivery unit and included all staff nurses. The project aimed to improve staff adherence to an existing Pitocin titration protocol. The project included preintervention data collection through chart audits from six months before the intervention, a 30-minute educational intervention with the introduction of a checklist tool administered at five opportunities over one month, and postintervention data collection through chart audits for three months postintervention. I performed statistical analysis of the data in SPSS using an independent samples t test or chi-square analysis to evaluate for a significant difference in staff adherence to the Pitocin titration policy postintervention, as well as for a significant difference in patient outcomes. The risks to the study participants were minimal, and their participation anonymized by all data collected being completely deidentified.
Chapter 4: Results

Purpose of the Project

I conducted this project on the labor and delivery unit of a community hospital. The purpose of this project was to increase staff adherence to the evidence-based Pitocin titration protocols in place at a community hospital labor and delivery unit. This project was based on the hypothesis that increased staff adherence to the policy would result in a decrease in adverse outcomes while improving the delivery of safe patient care. Based on available studies, if staff adherence to the protocol increased, a decrease was expected in the maximum Pitocin rate used, length of labor augmentation, rates of cesarean delivery for fetal distress or failure to progress, uterine rupture, incidence of low Apgar scores, incidence of tachysystole, and postpartum hemorrhage (Krening et al., 2012; Martin et al., 2013; Rohn et al., 2015; Sundin et al., 2018; Wojnar et al., 2014).

Demographics

I invited all 34 registered nurses employed in the unit to participate in the study. Of the 34 invited, 25 were full-time nurses and nine were as-needed nurses; seven nurses were over the age of 50, and 27 nurses were ages 24 to 49. There were six nurses who had less than five years of obstetrical nursing experience, 20 nurses who had 6–19 years of obstetrical nursing experience, and seven nurses with more than 20 years of obstetrical nursing experience. There were 11 nurses who were new to the organization in the six months prior, having been recently hired following the closing of a nearby hospital’s labor and delivery unit. Of the 34 nurses, 28 participated in the intervention, a participation rate of 82%. Of the 28 nurses who participated in the intervention, one terminated employment in the months following the intervention.
Data Analysis

I identified charts for data collection based on the categorization of labor augmentation in the labor delivery record. For the six-month period before the intervention began, 198 charts were identified as augmented labors. Of these 198 charts, 96 were excluded based on the stated exclusion criteria. A total of 102 charts for the preintervention period underwent audit. For the period spanning three months after the intervention, 109 charts were identified as augmented labors. Of these 109 charts, 39 were excluded based on the stated exclusion criteria. A total of 70 charts underwent audit for the postintervention period.

I ran a priori power analysis to determine the sample size needed to show statistically significant results that are generalizable. This analysis used a power of .80 and a medium effect size, and was used to determine that a total sample size of 128 was needed, or 64 for each group. The number of charts that met inclusion criteria for data collection was sufficient to meet this requirement.

After a review of the data collected, a paired-samples t test could not be used to compare the groups of data as planned, as the sample sizes were not the same. I used independent samples t test or chi-square analysis to analyze and compare the pre- and postintervention data for statistically significant changes in protocol adherence and secondary effects of adherence. I used a p value of 0.05 or less to indicate a statistically significant difference in the mean values of the two data sets for the t test and the frequency values for the chi-square analyses. Additionally, I evaluated the effectiveness of the educational intervention using a pre- and posttest design. I administered the posttest 1 month following the completion of the educational intervention to assess knowledge retention. I compared mean scores using a one-sample t test.
**Results.** The educational intervention pretest score average was 3.43 (49.0%). Posttest score average was 4.39 (63.0%), an increase from pretest scores. I tested the difference in test scores for normality and found scores to be normally distributed. I used a one-sample t test to compare the mean pretest score to the mean posttest score, as the scores were collected anonymously and could not be paired for a paired samples t test. The analysis determined that the difference was statistically significant (see Table 1).

Table 1

*One-Sample Test*

<table>
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<tr>
<th></th>
<th>t</th>
<th>df</th>
<th>Sig. (2-tailed)</th>
<th>Mean difference</th>
<th>95% CI of the difference</th>
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<tr>
<td>Posttest score</td>
<td>4.944</td>
<td>27</td>
<td>.000</td>
<td>.963</td>
<td>.56</td>
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</tbody>
</table>

*Note.* Test value = 3.43

A chi-square analysis was used to evaluate the relationship between the educational intervention and the adherence rate to the Pitocin titration protocol. There was a statistically significant difference ($p = .000$) in the rate of adherence between the pre- and postintervention data sets (see Table 2). For the preintervention group, the rate of adherence to the protocol was 58.6%; postintervention adherence was 73.5%.
Table 2

*Chi-Square Tests for Protocol Adherence*

<table>
<thead>
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<th>Test</th>
<th>Value</th>
<th>df</th>
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<th>Exact sig. (2-sided)</th>
<th>Exact sig. (1-sided)</th>
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<tbody>
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<td>Pearson chi-square</td>
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<td>.000</td>
</tr>
<tr>
<td>Continuity correction(^b)</td>
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<td>.000</td>
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<tr>
<td>Likelihood ratio</td>
<td>13.936</td>
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<td>.000</td>
<td>.000</td>
</tr>
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<td>Fisher's exact test</td>
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<td></td>
<td></td>
<td>.000</td>
<td>.000</td>
</tr>
<tr>
<td>Linear-by-linear association</td>
<td>13.581</td>
<td>1</td>
<td>.000</td>
<td>.000</td>
<td></td>
</tr>
<tr>
<td>(^a)0 cells (0.0%) had an expected count less than 5. The minimum expected count was 78.98. (^b)Computed only for a 2x2 table.</td>
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</tr>
</tbody>
</table>

Secondary data analysis evaluated the effect of increased protocol adherence on patient outcomes for the following data points: maximum Pitocin rates achieved, the total length of augmentation time, the frequency of category II and category III fetal heart tracing documented, 1-minute and 5-minute Apgar scores, and the pre- and postintervention frequency of postpartum hemorrhage, uterine rupture, placental abruption, primary cesarean delivery, and operative vaginal delivery (see Figure 2).
Figure 2. A bar chart illustrating trends for outcomes measures pre- and postintervention. Frequency of maternal/fetal outcomes are shown for the six months prior to the intervention and compared to the three months following the intervention.

**Maximum Pitocin rates.** There was a decrease in maximum Pitocin rates achieved in the postintervention group ($M = 6.26$) compared to the preintervention group ($M = 7.67$). However, an independent samples $t$ test did not show this difference to be significant ($p = .058$).

**Length of augmentation.** There was an increase in the total length of time Pitocin was used for augmentation in the postintervention group ($M = 6.02$) compared to the preintervention group ($M = 5.75$). An independent samples $t$ test did not show this difference to be significant ($p = .691$).

**Frequency of category II and category III fetal heart rate tracings.** There were no documented incidents of category III FHR tracings for either group. There was a decrease in
category II FHR tracing in the postintervention group \((M = 6.06)\) compared to the preintervention group \((M = 6.48)\). An independent samples \(t\) test did not show this difference to be significant \((p = .690)\).

**Apgar scores.** There was minimal difference in the 1-minute \((M = 7.99, M = 7.97)\) and 5-minute \((M = 8.77, M = 8.80)\) Apgar scores for the preintervention group and the postintervention group. This difference was not significant \((p = .936, p = .858)\) when compared with independent samples \(t\) test.

**Frequency of postpartum hemorrhage.** The frequency of postpartum hemorrhage increased from 3.9% in the preintervention group to 5.7% in the postintervention group. Assumptions for a \(2 \times 2\) table were violated; therefore, I used Fisher’s exact test to interpret the difference, which was not statistically significant \((p = .717)\).

**Frequency of uterine rupture.** There were no documented uterine ruptures for either group.

**Frequency of placental abruption.** The frequency of placental abruption decreased from 1.0% in the preintervention group to 0.0% in the postintervention group. Assumptions for a \(2 \times 2\) table were violated; therefore, I used Fisher’s exact test to interpret the difference, which was not statistically significant \((p = 1.00)\).

**Frequency of cesarean delivery.** The frequency of cesarean delivery decreased from 14.7% in the preintervention group to 10.0% in the postintervention group. Chi-square analysis did not show this difference to be significant \((p = .364)\). Among cesarean deliveries, the frequency of delivery for nonreassuring heart tones decreased from 9.8% to 2.9%, and the frequency of delivery for failure to progress increased from 4.9% to 7.1%. Fisher’s exact test did not show this difference to be significant \((p = .172)\).
**Frequency of operative vaginal delivery.** The frequency of operative vaginal delivery using vacuum or forceps decreased from 7.8% in the preintervention group to 7.1% in the postintervention group. Chi-square analysis did not show this difference to be significant ($p = .787$).

**Reliability/Validity**

The nature of the data collection lent itself to reliability and validity if executed properly, as chart audits collected descriptive data. Vassar and Holzmann (2013) identified 10 common errors in methodology when using retrospective chart review as a means of data collection. These errors in methodology were anticipated and accounted for, as discussed individually below.

**Well-defined research questions.** Vassar and Holzmann (2013) identified the lack of a well-defined research question before data collection as one of the common mistakes made in using chart audits as a means of data collection. I addressed this issue by clearly defining a research question before the initiation of the project. Based on the defined research question, I identified data points that directly measured the elements described in the research question.

**A priori sampling analysis.** Consideration should be given to how large of a sample size is needed to detect statistically significant differences between groups of data and the method by which this sampling would be performed. Sample size can be calculated using a power analysis. The sampling method can be convenience sampling, random sampling (the preferred method), or systematic sampling. I accounted for sample size by performing an a priori power analysis to indicate the minimum number of patient records needed for each group to be able to detect any statistically significant difference. The sampling method was not applicable, as data collection
occurred on a discrete type of patient record; therefore, all patient records that met inclusion and exclusion criteria underwent an audit.

**Operationalizing variables.** Operationalization of variables refers to the identification of data points that define the variables undergoing evaluation. For this study, this process was straightforward, as the variables undergoing evaluation were discreet and not open to interpretation (i.e., the maximum Pitocin rate documented).

**Training of data collectors.** It is important to maintain validity in data collection by training all data collectors to perform the task in the same manner. This was not an issue with this study, as there was only one data collector.

**Standardized data collection forms.** Vassar and Holzmann (2013) identified failure to use a standardized collection form as a common mistake, lending itself to errors and inconsistencies in data collection. Before the initiation of this project, development of a chart audit tool for all data abstraction occurred. There was only one data collector, so coding for each data point was consistent.

**Procedure for data collection.** Vassar and Holzmann (2013) recommended the use of a procedural manual to clarify the data collection process and decrease errors and inconsistencies. A procedural manual was not necessary for this project, as only one person conducted the data collection, and the chart audit form clearly defined the data points required for data collection.

**Inclusion and exclusion criteria.** Inclusion and exclusion criteria should be clearly defined as part of the procedural manual to further reduce errors and inconsistencies in data collection. While this project did not have a procedural manual, clear identification of inclusion and exclusion criteria for record identification did occur, which appeared on the chart audit form.
**Interrater reliability.** Cohen’s kappa can be used to evaluate interrater reliability, which would indicate the extent to which different data collectors code the data in the same way (Vassar & Holzmann, 2013). Interrater reliability was not an issue with this study, as there was only one data collector.

**Pilot testing.** Performing a pilot test before a full-scale research investigation can help identify issues with the study design, feasibility, and methodology. There was not a pilot study conducted before this project initiation. During the data collection process for this study, there was evidence of some issues with the data collection points that could decrease the usefulness of the study data.

**Confidentiality and ethical considerations.** It is important to consider confidentiality and ethics when conducting research involving human subjects, whether directly or indirectly. For this study, I obtained IRB approval from ACU and the PIRB before initiation. All efforts were made to decrease the personal health information accessed, and once this information was no longer necessary, it was destroyed.

**Summary**

The data supported the hypothesis that appropriate adult learning techniques would result in increased adherence to a protocol on a labor and delivery unit at a community hospital. There was a statistically significant increase in knowledge postintervention, as well as statistically increased adherence to the protocol. Secondary effects of protocol adherence were not shown to have significant improvements in outcomes, and all but two categories showed improving trends.
Chapter 5: Discussion, Conclusions, and Recommendations

The findings of this study have implications for practice and future research. While the findings support the main hypothesis that adult learning techniques and appropriate structure and process measures improve staff adherence to an existing protocol, the data did not support the expected improvement in secondary outcomes in a significant manner. Limitations of this study provide direction for future research to further the application of adult learning theory and quality improvement initiatives in the field of nursing.

Interpretation of and Inference From the Findings

The data supported Knowles’s adult learning theory that using adult learning techniques to present educational material to adult learners improves the success of knowledge retention and application for adult learners. The significant increase in adherence to the Pitocin titration policy in this unit indicates that the use of adult learning techniques, coupled with the structure measures of the quality improvement process, had the intended effect on the nursing staff in this unit. The implications for this finding are to present process changes and new education to nursing staff in a format consistent with adult learners to achieve a benefit to the learner and to ensure an increased rate of adherence to new protocols and policies in the facility. Adult learners want to know why the new material is important to them and how it will benefit them and their job performance. Donabedian’s quality of care framework was a useful guide for developing the structure, process, and outcomes measures for this study. Donabedian’s balancing measures will be useful to address the unintended outcomes and identified problems in the structure and process measures that provide limitations to this study.
Limitations. While adherence to the policy increased, the expected improvements in patient outcomes, while evident, were not statistically significant. Several limitations of this study could have contributed to this effect and warrant further investigation in future research.

Existing policy. Previous studies involving the implementation of a Pitocin titration policy exhibited significantly improved outcomes in maximum Pitocin rate used, length of labor augmentation, rates of cesarean delivery for fetal distress or failure to progress, uterine rupture, incidence of low Apgar scores, incidence of tachysystole, and postpartum hemorrhage (Krening et al., 2012; Martin et al., 2013; Rohn et al., 2015; Sundin et al., 2018; Wojnar et al., 2014). These studies, however, compared data on units that did not initially have a Pitocin titration policy in place to the outcomes following an initial protocol implementation. The unit that was the subject of the current study already had a titration policy in place, though nursing staff exhibited poor adherence to this policy. It stands to reason that there may not be significantly increased improvements in outcomes if the outcomes were not far from desirable initially.

Evaluation of adherence. In this study, adherence was measured by compliance with the protocol at the initiation of Pitocin infusion and each time the Pitocin infusion rate increased. The scope of the data collection did not consider adherence to the policy in instances where the infusion should have been decreased or stopped. While there was a significant improvement in the positive use of Pitocin titration, the data were not comprehensive enough to evaluate improvement in the negative use of Pitocin titration.

Checklist tool. The checklist tool in this project was a laminated sign placed in prominent view of all charting areas, designed to trigger the use of the protocol with each documentation of Pitocin increase. These signs could be easily overlooked or removed and do not guarantee that the nurse uses the tool. A more effective measure may be to have a mandatory
checklist embedded in the electronic medical record where documentation occurs, which forces a review of the protocol elements before documenting Pitocin initiation or a rate increase. Because this was a short-term project, there was not the time nor the evidence to support the build of a costly change to the electronic medical record.

**Physician support.** In the obstetrical inpatient unit, nurses and physicians work closely to coordinate the care of a patient in labor. It is imperative that this team work together cohesively to be effective. Previous studies suggested that the involvement of the entire care team in process changes is conducive to the successful implementation of new protocols (Doyle et al., 2011; Holmgren et al., 2011; Mandel et al., 2009). The policy that was the subject of this study was written and approved by the medical staff of this facility, and this policy did not undergo any changes as a result of this study. However, initial feedback indicated that among the physicians, there were myriad theories on the appropriate use of Pitocin, many of which did not line up with the facility-approved titration protocol.

**Unit census.** The unit in which this study took place had a recent influx of patients, an increase of approximately 60% (M. Foster, personal communication, March 22, 2019). With this increased census came increased staffing demand. On some days, the patient census exceeded the staffing capacity, an environment which lent itself to shortcuts and protocol nonadherence (Clarke & Donaldson, 2008; Kuwata, 2017). The data collection did not account for the effects of the unit census and busyness on protocol adherence.

**Implications of Analysis for Leaders**

The data analysis showed a significant increase in knowledge retention and application, as evidenced by improved adherence to a unit policy following the use of adult learning techniques and a quality improvement framework. These results suggest that nursing leaders will
achieve positive results on their units if the presentation of new policies and nursing education occur in a thoughtful way that gave credence to adult learning theories and the structured use of quality improvement processes, such as Donabedian’s quality of care framework. The positive trend in outcomes data following improved policy adherence, though not statistically significant, suggests that effective use of these theories in nursing education could benefit patient outcomes and measurable quality data, which is an increasingly important aspect of the culture of health care today.

In comparison to similar studies in the literature, this study emphasized the difference in rates of adherence when Knowles’s adult learning theory was not used in the rollout process versus when education tailored to adult learners accompanied the implementation. Nursing leaders who must evaluate quality data and devise plans for process improvements can benefit from the use of these techniques in future practice. Quality improvement is a necessary component of health care to receive maximum reimbursements for care and decrease the total costs of health care nationwide. Other financial implications for decreasing health care costs are the avoidance of litigation and associated costs, decreased costs of patient care when adverse outcomes requiring additional medical intervention are avoided, and decreased costs of patient care when operative delivery is avoided. Patient-centered care is at the core of the nursing mission and can only be achieved by continued research, investigation, and application of process improvement measures.

**Essentials of Doctoral Education for Advanced Practice Nurses**

**Essential I: Scientific underpinnings.** Safe patient care continues to be a central theme in the health care narrative today. Understanding treatment regimens and appropriately using medications and protocols is an essential element of safe patient care (Joint Commission, 2017).
A literature review of relevant studies in inpatient obstetrics revealed that appropriate use of Pitocin titration protocols resulted in improved outcomes and avoidance of patient harm (Krening et al., 2012; Martin et al., 2013; Rohn et al., 2015; Somprasit et al., 2005; Sundin et al., 2018). Knowles’s adult learning theory and Donabedian’s quality of care framework provided a theoretical foundation that guided the application of these literature findings in the clinical setting. An element of Doctor of Nursing Practice (DNP) Essential I focuses on “the nursing actions or processes by which positive changes in health status are affected” (American Association of Colleges of Nursing [AACN], 2006, p. 9). Integration of the science and knowledge of Pitocin, in conjunction with the evidence-based guidelines for titration and the theoretical foundations which guided this study, helps develop the skills of a DNP graduate, which will influence and inform future clinical practice.

**Essential II: Organizational and systems leadership.** Quality improvement and systems thinking are essential elements in successful leadership for a doctoral-level nurse (AACN, 2006). Outcomes of this study indicated the usefulness of these qualities in the inpatient obstetrical setting, as evidenced by increased protocol adherence and improved patient outcomes. Integrating improvements in quality of care, with sensitivity for organizational politics and populations, are future implications for the DNP graduate in this area of study and can have positive results on patient outcomes and risk management for this setting (Johnson & Sollecito, 2020).

**Essential III: Clinical scholarship and analytical methods.** The evaluation and application of evidence-based research to clinical practice is a cornerstone of doctoral nursing. As a result of this study, DNP graduates can develop the analytical skills necessary to evaluate the strength and implications of existing research and design appropriate research methods and
data collection tools for meaningful application of this research. This study reveals implications for the development of future data collection and assessment of protocol adherence on a nursing unit. Results of this study support the future use of quality improvement methodologies and theories applied in this study and will help guide the development of quality improvement initiatives in inpatient nursing.

**Essential IV: Information systems/technology.** Results of this study had implications for the use of embedded clinical decision tools in the future success of protocol adherence. DNP graduates can assess clinical situations and evaluate for the usefulness of patient care technology, including meaningful use of the electronic health record for specialty areas of clinical care (AACN, 2006). Following this study, recommendations for clinical research and practice call for the application of this essential to further the support of safe patient care.

**Essential V: Health care policy.** The development of this project and feedback received from stakeholders reveals the implications for involvement in the policy process within the institution to facilitate improved health care delivery. The DNP graduate must be able to evaluate policy from the viewpoint of all stakeholders and influence positive change through the policy-making process (AACN, 2006). Lack of physician support for this quality improvement initiative underlines the importance of involvement from all stakeholders in successfully implementing policy change at the institutional level.

**Essential VI: Interprofessional collaboration.** As previously stated, an important aspect of policy and process change is the involvement of all stakeholders. This study focused on the implications for nursing education in protocol adherence; limitations of this study did not allow for full interprofessional collaboration. While physicians were invited to participate in education, they were not formally involved in the project development process or evaluation,
which caused some pushback in the nursing application of the education received. This provides support for the importance of this DNP essential and the impact of effective interprofessional collaboration.

**Essential VII: Clinical prevention and population health.** DNP graduates are proficient in the analysis and synthesis of concepts involved in clinical prevention and population health (AACN, 2006). Using evidence from this study and the implications for future research and clinical practice, DNP graduates can apply evidence-based methods for implementing care measures that prevent adverse outcomes in this clinical setting. Evaluation of current practice standards by the DNP graduate can be used to identify gaps between evidence-based recommendations and practice and facilitate the implementation of care delivery models that address these gaps and promote the health and safety of this population (AACN, 2006).

**Essential VIII: Advanced nursing practice.** A key component of this study was the application of Knowles’s adult learning theory to the introduction or reinforcement of clinically relevant information to clinical nursing staff. The results of this study highlight the importance of the role of the DNP graduate in applying evidence-based theories to the development and implementation of staff education in an effort to improve patient outcomes and in serving as a mentor to other nurses in the application of evidence-based practice in the clinical setting (AACN, 2006). Findings in this study implicate the need for interprofessional collaboration to promote quality and safe patient care. DNP graduates focus on the application of this essential through developing and maintaining interprofessional relationships that facilitate evidence-based care delivery and improved patient outcomes (AACN, 2006).
Recommendations for Future Research

**Method of implementation.** The methodology of this study applies to the implementation of new practice protocols or reimplementations of existing practice protocols on any inpatient nursing unit to evaluate for similar results. Using adult learning theory and an evidence-based quality improvement framework should be the basis for the introduction of new processes or reinforcement of existing process alike. Evaluation of improvement should take into consideration the baseline data and the ideal goals for the nursing unit.

**Evaluation of adherence.** Application of this study design for future research should take into account all aspects of protocol adherence to comprehensively evaluate for significant improvement. Adequate time and resources should be set aside to accommodate the need for intensive data collection for this type of analysis. Controlling for contributing factors, such as staffing, physician collaboration, and limitations of the electronic charting system, is an important element for future study design. Future analysis could also consider differences in adherence accounted for between shifts or between physician groups, who may have different practice tendencies.

**Interprofessional collaboration.** Future study designs should take a more collaborative approach, which may lend itself to improved success of the implementation. A meeting of all stakeholders, which allows for such collaboration, will ensure the inclusion of the ideas that are important to each group and encourage support from each group to design a successful quality improvement project. When attempting to improve adherence to a unified policy or protocol, it is key to have all departments involved working toward the same goal.

**Use of health information technology.** The use of health information technology is a key initiative of health care reform. Embedded clinical decision tools are useful for guiding
evidence-based care. Investment in such tools provides a structure to the standard of care delivered to each patient and ensures the use of the most current evidence-based clinical guidelines (Centers for Medicare & Medicaid Services, 2018). Incorporating this technology in future studies of protocol adherence may yield more positive results and achieve significant improvements in adherence and patient outcomes.

**Conclusion**

Patient safety and outcomes are key components of today’s health care field. This study was designed to address how applying adult learning theory in conjunction with an evidence-based quality improvement framework could be used to decrease adverse outcomes and to improve the delivery of safe patient care. The results of this study demonstrated the usefulness of combining these two elements to improve the dissemination of knowledge to nurses in clinical practice. Implications for nursing leaders call for changes to the development and implementation of quality improvement initiatives at the clinical level.
References


Appendix A: Chart Audit for Pitocin Titration Protocol Adherence Project

Chart # _____________

<table>
<thead>
<tr>
<th>Documented augmentation?</th>
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<tbody>
<tr>
<td>Term singleton gestation? (37 0/7 – 42 0/7)</td>
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<tr>
<td>Primip or Multip?</td>
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<tr>
<td>Comorbidities or other risk factors? (diabetes, hypertension, cholestasis, IUGR, maternal comorbidities, fetal anomalies, infection, TOLAC/VBAC)</td>
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<td>SROM or AROM?</td>
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<tr>
<td>Meconium stained?</td>
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<tr>
<td>Time labor started</td>
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<tr>
<td>Time of Pitocin initiation</td>
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<tr>
<td>Time of Pitocin discontinuation / delivery</td>
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<tr>
<td>Maximum Pitocin rate achieved</td>
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<tr>
<td>Criteria met for initiation?</td>
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<tr>
<td>Criteria met for each increase in Pitocin rate?</td>
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<td>4</td>
<td>18</td>
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<td>6</td>
<td>20</td>
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<td>14</td>
<td>28</td>
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<tr>
<td>16</td>
<td>30</td>
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<tr>
<td>IUPC placed if Pitocin rate above 20?</td>
<td></td>
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<tr>
<td>Number of times Category II tracing is documented</td>
<td></td>
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<tr>
<td>Number of times Category III tracing is documented</td>
<td></td>
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<tr>
<td>Apgar score 1 minute</td>
<td></td>
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<tr>
<td>Apgar score 5 minute</td>
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<tr>
<td>Postpartum Hemorrhage?</td>
<td></td>
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<tr>
<td>Uterine Rupture?</td>
<td></td>
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<tr>
<td>Type of delivery? (Vag-SPONT, Vag-VA, Vag-FA, CSX-FTP, CSX-NRHT)</td>
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</table>
Appendix B: Sample Slides From Education Intervention

Objectives

- Understand why safe Pitocin use is important to obstetrical nurses
- Understand how Pitocin works to facilitate labor and delivery
- Understand how to follow the titration protocol

What’s all the Fuss?

- Misuse of Pitocin is one of the top five causes of preventable perinatal harm
- Misuse of Pitocin is frequently the subject of obstetrical medical liability cases, and accounts for half of all paid obstetric litigation claims
- Associated adverse effects from misuse of Pitocin include maternal and fetal harm and/or death
- 50% of all labors use Pitocin for induction or augmentation
- The Institute for Safe Medication Practices placed Oxytocin IV on the list of high-alert medications in 2007
The Basics of Oxytocin

- Synthesized in the hypothalamus and secreted by the anterior pituitary
- Synthesized and secreted by the lining of the uterus, corpus luteum, amnion, and placenta
- Labor is manipulated by the up-regulation of receptor sites on the uterus and feedback cycles

How Does Oxytocin Affect Labor?

- Pulsatile release from pituitary
- Calming, stress-reducing, and analgesic effects
- Up-regulation of oxytocin receptors
  - More concentrated at fundus
  - Receptor expression and sensitization increases at term
  - Physiologic labor contractions are ~ 4 in a 10 minute period
Appendix C: Pretest/Posttest

Understanding Pitocin

1. The synthetic IV form of Oxytocin (Pitocin) functions in the same manner as the endogenous Oxytocin that is produced by the pituitary gland.

   TRUE    FALSE

2. The higher the rate of infusion, the stronger and more frequent uterine contractions will be.

   TRUE    FALSE

3. The half-life of Pitocin is

   a) 3–6 minutes    c) 15–20 minutes
   b) 10–15 minutes  d) 20–30 minutes

4. The time it takes for a dose of Pitocin to reach steady state is

   a) 10 minutes    c) 30 minutes
   b) 15 minutes  d) 40 minutes

5. Following a uterine contraction, it takes ____________ for blood flow to be fully restored to the placenta and for fetal oxygen saturation levels to return to precontraction state.

   a) 40 seconds    c) 90 seconds
   b) 60 seconds    d) 120 seconds

6. Oxytocin receptors (OTRs) can become desensitized over time.

   TRUE    FALSE

7. Match the terms to the correct definitions.

   A. Tachysystole   B. Hyperstimulation   C. Hypertonus

   _____ An increase in intrauterine pressure between contractions
   _____ An increased frequency of naturally occurring contractions
   _____ An increased frequency of contractions in the presence of Pitocin administration
Appendix D: Checklist Tools

Checklist Tool for Computer Screens

Initiating or Increasing Pitocin? **STOP AND THINK!**
- Are the FHT’s a Category I?
- Are the contractions less than 5 in 10 minutes?
- Are the MVU’s less than 200?

*If the answer to any of these questions is “NO”, you SHOULD NOT increase the Pitocin.*

Checklist Tool for IV Pumps

Initiating or Increasing Pitocin?

**STOP AND THINK!**
July 22, 2018

TO: Whom it May Concern

FROM: Beverly Welch, MSN, RN, NEA-BC

RE: Letter of Support for Capstone Project

This is an official Letter of Support for the capstone project submitted to [redacted] by Tara Cassell which is intended to educate the Labor and Delivery team on the pharmacokinetics of Pitocin and the appropriate use of the titration protocol with the creation and implement an assessment tool. The project is intended to improve adherence to policy and protocol for Pitocin titration. The project is was selected by Tara because Pitocin is one of the top five causes of preventable perinatal harm, and allegations of inappropriate Pitocin use accounts for half of all paid obstetric litigation claims.

We are excited to participate in this project whose progress will be tracked through our Women's Service Line Leader Mindy Foster, MSN, RN. Tara will present her capstone project upon completion to our Patient Safety Committee and to Women's Service Line. If you have any questions, please feel free to contact me at [redacted]
Appendix F: IRB Approval Letters

Dear Tara,

On behalf of the Institutional Review Board, I am pleased to inform you that your project titled "Comprehensive Staff Education and Implementation of a Checklist Tool to Increase Staff Adherence to Pitocin Titration Protocols" (IRB# 15-070) is exempt from review under Federal Policy for the Protection of Human Subjects.

If at any time the details of this project change, please resubmit to the IRB so the committee can determine whether or not the exempt status is still applicable.

I wish you well with your work.

Sincerely,

Megan Roth

Megan Roth, Ph.D.
Director of Research and Sponsored Programs
DATE: November 6, 2018

TO: Tara Cassell, MSN

PROJECT TITLE: [1330343-1] Comprehensive Staff Education and Implementation of a Checklist Tool to Increase Staff Adherence to Pitocin Titration Protocols

SUBMISSION TYPE: New Project

STATUS: Active

ACTION: APPROVED

APPROVAL DATE: November 5, 2018

EXPIRATION DATE: November 4, 2019

REVIEW TYPE: Expedited Review

REVIEW CATEGORY: Expedited review category # 3, 7

Thank you for your submission to the institutional Review Board has APPROVED your submission. All research must be conducted in accordance with this approved submission.

Note to Principal Investigator:

1. [redacted] has administratively revised the consent form included in this submission. You are required to use the revised consent form to enroll the nurse participants. As such, the following documents have been reviewed and revised as part of this approval:

   * Other - TRACKED: Revised Consent Form
   * Other - CLEAN: Revised Consent Form (Please Use for Future Submissions)
   * Stamped Document - APPROVED FOR USE: Revised Consent Form

The above listed documents can be found under the "Reviews" tab in IRBNet. If you would like to make further changes to the consent form, please submit an Amendment/Modification through IRBNet.

This study meets the criteria for a waiver of informed consent for the patient participants according to federal regulations pertaining to human subject research.

Informed consent is a process that must continue throughout the duration of the study via a dialogue between the researcher and the research participant. Federal regulations require that informed consent be documented by the use of a written consent form approved by the IRB and signed by the research participant or the participant’s legally authorized representative. Federal regulations also require that each participant receive a copy of the consent form.

Please note that it is your responsibility to obtain any additional local institutional or departmental required approvals prior to initiating your study.
Any revision to previously approved materials must be reviewed and approved by the __________ prior to implementation, except when necessary to eliminate apparent immediate hazards to the subject. If, during the course of the research, it becomes necessary to modify the study to eliminate apparent immediate hazards to research participants, you are required to notify the IRB by submitting a study modification. Please submit modifications through IRBNet, and use the appropriate revision forms for this procedure.

The __________ requires prompt reporting (within 10 business days of discovery) of events that are Unanticipated Problems. Unanticipated Problems are 1) unanticipated AND 2) serious or life-threatening or potential for increased risk AND 3) possibly or definitely related to the protocol, as determined by the investigator. Unanticipated deaths that meet these 3 criteria must be reported to the __________ within 24 hours of discovery. Events that are not Unanticipated Problems may be reported to the __________ in summary form at the time of continuing review. All FDA and sponsor reporting requirements should also be followed.

All major protocol departures regarding this study must also be reported within 10 business days to this office. Major protocol departures are events that impact the risk and benefit of the research; may impact subject safety; affect the integrity of research data and/or affect a subject's willingness to participate in the research. All minor protocol departures can be reported at the time of continuing review.

Please submit your continuing review through IRBNet, and use the appropriate forms. Your documentation for continuing review must be received with sufficient time for the __________ to review and to issue approval. Your study expires on November 4, 2019, and your continuing review should be submitted to the __________ 45 days prior to this expiration date. The __________ will send reminder emails prior to study expiration, but it is the responsibility of the investigator to provide continuing review documentation to the __________ for continued approval of this study.

Please note that all research records must be retained for a minimum of three years after the completion of the project. Consent forms, including those for optional procedures, or other study documents pertaining to HIPAA, must be maintained for at least 6 years after the end of the study.

The following documents have been approved or noted as part of this approval:

- __________ Research Application (UPLOADED: 10/25/2018)
- Data Collection - Chart Audit form.docx (UPLOADED: 10/8/2018)
- Other - Letter of Support Tara Cassell.docx (UPLOADED: 10/10/2018)
- Other - checklist tool.docx (UPLOADED: 10/8/2018)
- Questionnaire/Survey - Pre-test Post-test.docx (UPLOADED: 10/8/2018)
- Cover Sheet - __________ cover_letter (1).pdf (UPLOADED: 10/11/2018)
- **NOT APPROVED FOR USE** - Consent Form - Informed Consent.docx (UPLOADED: 10/8/2018)
- **OBSCURE** - HIPAA Waiver __________ Waiver or Alteration of Authorization Request Form v 05 JUN 2015.doc.pdf (UPLOADED: 10/25/2018)

If you have any questions at any time, please feel free to contact the __________ or __________. Please include your project title and reference number in all correspondence with the __________ so that we can best assist you.

Thank you.
### Appendix G: Project Timeline

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